MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

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The Honorable Leonard Lance
133 Cannon House Office Building
Washington, DC 20515

Dear Representative Lance,

On behalf of the Medical Device Manufacturers Association (MDMA), I would like to express our strong support for the bipartisan FDA SOS Act which would exempt Food and Drug Administration user fees from sequestration. MDMA represents hundreds of innovative and entrepreneurial medical technology companies, many of which independently contribute user fees to FDA in order to ensure that patients get timely access to safe and effective products.

It is estimated that the Center for Devices and Radiologic Health (CDRH) would lose approximately $2.9 million in user fees for fiscal year 2013 and approximately $16 million in total fees if the sequester is not exempted. These are private sector dollars paid by companies as a result of negotiated agreements among FDA, industry and Congress. It is not appropriate for industry funded monies to be included in sequester related appropriation reductions.

The most recent authorization of the Medical Device User Fee Program, MDUFA III, resulted in increased user fee payments in return for greater accountability, predictability and transparency from FDA as well as the hiring of additional staff. The goal of these negotiations was to decrease review times without sacrificing safety in order to provide patients and physicians with timely access to life-saving products and therapies.

In the end, we must protect FDA's important goals of achieving safe, efficient and timely review of life-saving medical products and devices.

Thank you for your leadership on this critical issue. I look forward to working with you to ensure that the FDA SOS Act becomes law.

Sincerely,

Thomas C. Novelli

Thomas C. Novelli
Vice Presient of Government Relations
Medical Device Manufacturers Association